DEPARTMENT OF HEALTH & HUMAN SERVICES

M977N

Public Health Service

4/11/97

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

MAY 30 1997

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref. No.: 97-HFD-340-0501

Ernst L. Wynder, M.D.
President, American Health Foundation
One Dana Road
Valhalla, New York 10595

Dear Dr. Wynder:

During January of 1997, Ms. Margaret E. Sarles, investigator with the Food and Drug Administration (FDA) New York District, inspected the nonclinical laboratory facilities of American Health Foundation, Valhalla, New York. The purpose of the visit was to assess the facility's compliance with the Good Laboratory Practice (GLP) regulations, Title 21, Code of Federal Regulations, Part 58. At the same time, she reviewed four nonclinical toxicity studies.

During the inspection, she observed several deviations from the GLP regulations. These findings were listed on an Inspectional Observations Form FDA-483 (copy enclosed), which was presented to, and discussed with, Dr. Michael J. Iatropoulos, Head, Regulatory Pathology and Histology, at the conclusion of the inspection.

We have reviewed the deficiencies listed on the Form FDA-483, the inspection report, and other data collected during the inspection and conclude that the conditions are serious violations of the GLP regulations and that there appears to be a failure of management, study directors, and the quality assurance unit to exercise their responsibilities as required by Parts 58.31, 58.33, and 58.35 of the GLP regulations. Unless these deficiencies are corrected, we would consider future studies conducted at this facility to be seriously flawed. Further, such studies could be excluded from consideration for support of a research permit or marketing application for products regulated by this agency.

We request that you respond to this letter in writing within fifteen (15) working days of receipt of this letter and indicate to us your intentions to either immediately correct the GLP violations or assure the Agency that there will be no further studies conducted that are subject to FDA GLP requirements until corrections are made and verified.

Your response should include (1) the specific steps you have taken or are taking to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations; (2) the date corrections will be completed; and (3) any documentation to indicate correction has been achieved.

We consider these violations a serious matter and urge you to respond promptly. Failure to do so may result in further agency action.

If you have any questions regarding this matter, or the Good Laboratory Practice regulations, please contact:

C. T. Viswanathan, Ph.D.
Associate Director
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research
7520 Standish Place, Room 102
Rockville, Maryland 20855
Telephone: (301) 594-1023

Sincerely yours,

David A. Lepay, M.D., Ph.D
Director
Division of Scientific Investigations
Office of Compliance
Center for Drug Evaluation and Research

Enclosure: Form FDA-483

cc:

Michael J. Iatropoulos, M.D., Ph.D.
Head, Regulatory Pathology and Histology
American Health Foundation
One Dana Road
Valhalla, New York 10595

cc:

Francisca E. Liem, Chief
Laboratory Data Integrity Branch
Office of Enforcement and Compliance Assurance
U S Environmental Protection Agency
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